



# Guidance for Meeting the Training Requirements of the Select Agent Regulations

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## Preface

**Revisions:** This is a living document subject to ongoing improvement. Feedback or suggestions for improvement from registered Select Agent entities or the public are welcomed. Submit comments directly to the Federal Select Agent Program at:

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## Introduction

Effective training is an essential component of successful safety and security programs. The regulatory requirements for training are found in Section 15 of the select agent regulations. Individuals that access select agents and toxins must know the requirements of their entity's safety, security, and incident response programs if their entity is to be compliant. The regulations define the training that must be provided, who must receive the training and how often the training must be provided. The Responsible Official (RO) must ensure that the individuals in their entity who are required to be trained are provided information and trained in the areas specified, that they understand the training, that they are trained at least annually, and that the training is documented.

## Training Required

The training that must be provided is described in Section 15(a) of the select agent regulations, which states that registered individuals or entities must provide information and training on biosafety, security (including security awareness), and incident response to:

- individuals listed on the entity's registration who have been approved for access to biological select agents and toxins from the HHS Secretary or Administrator and;
- other individuals, although not approved for access to select agents and toxins, who enter areas where select agents or toxins are handled or stored (visitors).

Thus, the entity that is required to register to possess, use and transport must provide information and training in biosafety, security and incident response. Security awareness must be part of the security training. All individuals with approved security risk assessments (SRA) must undergo a general initial training which provides site-specific information on biosafety, security, and incident response. Refresher training on this information must be provided annually to all SRA approved individuals. Select agent and toxin specific training is provided based on an individual's access or potential for access to select agents and toxins and their scope of work with select agents and toxins.

The regulations state that "the training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents and toxins," but do not state that the training must be specific to the entity. However, the training will not be of much help to the entity's staff if they cannot put it in the context of the safety policies and procedures at the entity. This is not to suggest that the entity cannot use training programs that may be available from educational resources, but an entity should ensure that training specific to the entity is also included. It may also be possible for entities to join others in the area to do joint training to help defray costs. If the entity uses this approach, it should ensure that this training is complemented with entity-specific training.

It is important that the training program is kept up to date and any changes in entity policies or procedures are incorporated into the training programs. Anytime a new research project is planned, new facilities or equipment is added, or the entity plans to work with different agents or toxins, the RO should review the program to confirm that it is still meeting the regulatory requirements. Occasionally there are changes in the regulations made by the Federal Select Agent Program. The RO should ensure that changes affecting the entity are incorporated into the entity's training program.

The regulations do not specifically require the RO to develop the training program or to personally conduct the training for the entity but under Section 9 (Responsible Official), the RO is required to ensure that the training is conducted and documented. The RO may delegate the training responsibilities to other entity staff. There may be a number of resources both internally and externally that are available to the RO to help with the training requirement.

There are no specifications in the regulations on what is considered an acceptable training program. The entity has a wide range of options for how to set up a training program. An entity could develop a "PowerPoint" presentation that covers the basics. Another approach is to require the staff to read the appropriate standard operating procedures or the appropriate plans. On-line self-study training

programs are also ways some entities provide training. An entity may have staff members of the organization give presentations. An example might be security training that is led by the head of security at the institution. The training may also be provided by outside experts such as someone from the community (e.g., community's hazardous response team) or someone from the Federal Bureau of Investigation's Weapons of Mass Destruction regional office.

Please note that the entity must provide training and employ methods to verify that the individual understood the training. If the entity provides information on what personal protective equipment must be used before entering the "BSL-3" laboratory but does not provide instruction on how to put the equipment on and take it off then the entity has only provided information and not training. Some entities will combine classroom presentations with a mentoring program. This provides both information (classroom) and training (mentoring). Other entities may ask the individual to read the biosafety manual, acknowledge that they have read it, and verify that they understood the information.

Biosafety training should consist of how to work with select agents and toxins in a safe manner. Examples of the types of topics that should be addressed include: how to use the biosafety cabinet, what kind of personal protective equipment is required and how to use the equipment, what to do if there is a spill, how to prepare and use disinfectants, and the specific hazards of the select agents or toxins the entity uses.

Security training should consist of information on how to protect the select agents and toxins from loss. Examples include what to do if a staff member loses their key or identification badge, what to do when encountering someone in the laboratory who is not authorized, who to notify if select agents or toxins are found missing, and what to do if a suspicious package is discovered. Examples of security awareness include how to recognize breaches in security and who to notify, what to do if a colleague is displaying unsafe or suspicious behaviors, and what to do if individuals who are not part of your organization are asking specific questions about security procedures.

Incident response training should consist of information on how to react to emergencies. Examples include the correct response if the fire alarm goes off, how to exit containment in an emergency, what to do if a colleague collapses in containment, where to go if there is a tornado warning and what to do if the air handling system malfunctions.

### **Specific Work Related Training**

Training must be provided to address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. An entity must ensure that the training provided is appropriate for the work that the employees are performing. For example, the engineer who maintains the air handling systems would not require the same type of biosafety training as the laboratory technician who conducts animal research with *Bacillus anthracis* using aerosol equipment. The training that each receives should be designed to ensure that they can carry out their responsibilities without causing harm to themselves or to their fellow co-workers and the public.

The entity is able to meet this requirement in several ways. One way is to provide general training in safety, security and incident response which everyone would participate in and then specific training

would be provided to individuals depending on the work they perform. For example, the animal technician would be provided the training on the risk presented by infected animals while the engineer would be trained on how to ensure equipment is decontaminated before conducting maintenance. Another option is for the entity to separate individuals into groups by the risk posed and provide the appropriate training to each of these groups. Some entities may require the principal investigator or the laboratory manager to be responsible for developing and conducting the agent specific training. If this is the approach used it is important that the RO ensure the training provided meets the regulatory requirements and is consistent.

## **Tier 1 Biological Select Agents and Toxins Training**

There is a specific training requirement for those entities that possess Tier 1 biological select agents and toxins (Tier 1 BSAT) in Section 15(b) that states: “Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.”

Any entity that has Tier 1 BSAT as identified in the select agent regulations must conduct annual insider threat awareness briefings. The Federal Select Agent Program Security Guidance and Suitability Assessment Guidance documents provide information on insider threat awareness briefings and should be consulted. These briefings must be part of the individual’s training records. Transient visitors to the laboratory would not be expected to receive this type of training because they do not have sufficient knowledge of the entity to serve as a reference.

## Training of Individuals

### Individuals with Access

The select agent regulations define who must receive training in Section 15(a)(1), which states: “...Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins;”

This requirement is for anyone who has received access approval from either the HHS Secretary or Administrator, through the SRA process to receive the required training before they are allowed to have access. An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.

Even though entities may list in their application a number of individuals, these individuals may never have access to the select agents and toxins but may have the potential to access these agents and toxins. If an individual receives approval to have access through the SRA process they must receive training in biosafety, security and incident response. It is important to emphasize that before an individual is allowed by the entity to access the select agents and toxins, they must have an approved SRA and they must have received training.

Some ROs may question whether a person who has just joined the entity and has many years of laboratory experience or may be a national leader in their field needs to receive the required training. The answer is if they go through the SRA process, they must receive the training. It is important to recognize that no matter how many years of laboratory experience the individual has every institution is unique; different floor plan, different equipment, different protocols, and policies. It is important for each new person to become aware of the features that are unique to the entity they join.

### Visitors

The select agent regulations also state in Section 15(a)(2) that “...Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.) Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored.”

The individual who does not have an SRA at that entity is not allowed to have access to select agents and toxins. If they enter any area where select agents and toxins are used or stored, they must first receive training and there must be documentation that the individual acknowledged receiving the training. These individuals must be escorted by a person who has an approved SRA. The type of training they receive must be appropriate for the risk that the person is likely to encounter in the area. The training that is provided is not expected to be as extensive as it is for those who have access to the select agents and toxins. It may consist of what to do if an alarm goes off, what personal protective equipment is required and how to put it on and take it off, which areas are not to be entered and what

to do if the visitor becomes ill after visiting the area. Recurring visitors must receive training once per calendar year.

It is important for the RO to ensure that everyone who is escorted into an area where select agents and toxins are used or stored has acknowledged receiving training before entering the area. The RO should occasionally check access records against training records to ensure that everyone who has access has received the required training.

### **RO Training**

The Federal Select Agent Program recognizes that the responsibilities of an RO require a broad spectrum of knowledge, skills, and abilities. The RO is evaluated by the Federal Select Agent Program on how they conduct their responsibilities and how well their entity maintains compliance with the regulations. This does not mean that the RO should not document any training they receive in biosafety, security and incident response, but only that specific documentation is not a requirement under the current regulations.

## Frequency of Training

The select agent regulations require that individuals receive refresher training in Section 15(c), which states: “Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.”

Training must be provided at least annually to anyone who has received access approval from either the HHS Secretary or Administrator (i.e., has a SRA). If the entity makes significant changes to the biosafety, security or incident response plans, then the entity needs to update their training programs and provide the training to the staff. Some examples of situations that require refresher training are:

- Renovation of the research building results in changes to biosafety, security and incident response policies and procedures.
- A principal investigator begins a new project with select agents that have not been used at the entity before and/or new protocols.
- The security system has been upgraded.
- The Federal Select Agent Program has made modifications to the regulations.
- Changes to the building have altered emergency access or egress routes.

In addition an overview to biosafety, security and incident response, refresher training does not necessarily need to be as extensive as the training a person receives when they first join the entity. Refresher training should at least consist of an overview of biosafety, security and incident response and also presents an opportunity to focus on specific topics. For example, the RO may want to focus refresher training on the causes of security breaches or releases of select agents that occurred during the previous year.

This section requires refresher training to be provided annually. The Federal Select Agent Program recommends that the time frame should be closer to a 12-month interval between annual refresher training events unless there is a reason for the training to occur sooner, such as significant alteration to an entity’s plan or procedure. The refresher training may incorporate biosafety, security and incident response into one training event or may divide these subjects into different training events.

Drills and exercises are required by the regulations to test the biosafety, security and incident response plans. Drills and exercises are excellent opportunities for a training experience. For example, in conducting an exercise on what to do when a person collapses in the laboratory, the individuals that participate in the exercise learn about biosafety and emergency response procedures. This satisfies the requirement to conduct a biosafety and incident response drill and it may also help to satisfy part of the refresher training requirement for those who participate. This may in part satisfy the refresher training requirement.

## Training Records

The select agent regulations require that records of training are kept for individuals in Section 15(d), which states “The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.” These records must be maintained for a period of at least three years. There is no specified method or system to record the training other than that the record must contain the name of the individual, the date they receive training, a description of the training provided and the means used to verify that the individual understood the training. Some entities will establish a file on each individual that includes all training the individual receives not just select agent training. Some entities will establish a checklist of all the training the person is required to take and the person providing the training signs the checklist when training has been provided. As long as the required information is maintained, any system is acceptable.

There must be a means for verifying that the individual understands the training that they receive. Some entities will give the individual a test to determine if they understood the material or ask that the individual sign the record that they understood the training. During an inspection by the Federal Select Agent Program, an inspector may interview staff members at random to assess their knowledge of biosafety, security and incident response.

All training records, including those for individuals who do not have an approved security risk assessment but go into an area where there are select agents and toxins, must also be maintained for three years. The RO must be able to produce a record that individuals who are escorted into laboratories with select agents and toxins have received instructions and have signed that they received and understood the instructions. Most entities will have a one or two page document listing the name of the individual who enters the area, the information and training they were provided and the signature of the individual verifying that they received the training.